

We Claim:

1. A method for administering a therapeutic agent to a predetermined area of skin or mucosa of a vertebrate subject, said method comprising:

(a) accelerating particles into, across or both into and across the area of skin or mucosa; and

(b) topically positioning a first transdermal drug delivery device or a first occlusive dressing over the area of skin or mucosa, wherein the particles or the first transdermal drug delivery device or the first occlusive dressing, or a combination thereof, comprise the therapeutic agent.

2. The method of claim 1, wherein the particles comprise the therapeutic agent.

3. The method of claim 1, wherein the particles comprise a placebo.

4. The method of claim 1, wherein the particles comprise therapeutic agent and a placebo.

5. The method of claim 1, wherein step (b) comprises topically positioning the first transdermal drug delivery device over the area of skin or mucosa.

6. The method of claim 5, wherein the first transdermal drug delivery device contains the therapeutic agent.

7. The method of claim 1, wherein step (b) comprises topically positioning the first occlusive dressing over the area of skin or mucosa.

8. The method of claim 7, wherein the first occlusive dressing contains the therapeutic agent.

9. The method of claim 3, wherein step (b) comprises topically positioning the first transdermal drug delivery device over the area of skin or mucosa, and further wherein the first transdermal drug delivery device contains the therapeutic agent.

5 10. The method of claim 3, wherein step (b) comprises topically positioning the first occlusive dressing over the area of skin or mucosa, and further wherein the first occlusive dressing contains the therapeutic agent.

10 11. The method of claim 1, wherein the particles comprise an antigen.

12. The method of claim 1, wherein the particles comprise an adjuvant.

15 13. The method of claim 11, wherein the method further comprises a pretreatment step to administer an adjuvant to the area of skin or mucosa before step (a).

14. The method of claim 13, wherein the pretreatment step comprises topically positioning a second transdermal delivery device or a second occlusive dressing containing an adjuvant over the area of skin or mucosa.

20 15. The method of claim 11, wherein step (b) comprises topically positioning the first transdermal drug delivery device or the first occlusive dressing over the area of skin or mucosa, and further wherein the first transdermal drug delivery device or first occlusive dressing contains an adjuvant.

25 16. The method of claim 1, wherein the particles comprise a permeation enhancing agent.

30 17. The method of claim 5, wherein the first transdermal delivery device is a passive transdermal delivery device.

18. The method of claim 5, wherein the first transdermal delivery device is an active transdermal delivery device.

5 19. The method of claim 1, wherein the particles are accelerated toward the target skin or mucosal surface using a needleless syringe device.

20. The method of claim 1, wherein the particles are accelerated toward the skin or mucosal tissue at a velocity of about 200 to 3,000 m/sec.

10 21. The method of claim 1, wherein the particles have a diameter predominantly in the range of about 0.1 to 250 μm .

15 22. The method of claim 2, wherein the particles comprise a biologically active protein, a peptide, an oligosaccharide, a polysaccharide or a vaccine composition.

23. The method of claim 1, wherein step (a) provides for rapid delivery onset from the first transdermal delivery device.

20 24. The method of claim 5, wherein the particles and the first transdermal delivery device comprise the same therapeutic agent.

25 25. The method of claim 7, wherein the particles and the first occlusive dressing comprise the same therapeutic agent.

26. The method of claim 4, wherein the placebo comprises particles selected from the group consisting of a metal particle and a metal particle coated with a permeation enhancing agent.

27. The method of claim 9, wherein the placebo comprises particles selected from the group consisting of a metal particle and a metal particle coated with a permeation enhancing agent.

5 28. The method of claim 10, wherein the placebo comprises particles selected from the group consisting of a metal particle and a metal particle coated with a permeation enhancing agent.

10 29. The method of claim 6, wherein the particles comprise a permeation enhancing agent.

30. The method of claim 8, wherein the particles comprise a permeation enhancing agent.

15 31. The method of claim 1, further comprising before step (a), topically positioning over the area of skin or mucosa a second transdermal delivery device or a second occlusive dressing.

20 32. The method of claim 31, wherein the second transdermal delivery device or the second occlusive dressing contains a permeation enhancing agent.

33. A method for administering a therapeutic agent to a predetermined area of skin or mucosa of a vertebrate subject, said method comprising administering to said area of skin or mucosa (i) particles comprising a therapeutic agent, and (ii) placebo particles,
25 wherein said particles are accelerated into, across or both into and across the area of skin or mucosa.

34. The method of claim 33, wherein the particles comprising the therapeutic agent and the particles comprising the placebo are administered simultaneously.

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35. The method of claim 33, wherein the particles comprising the therapeutic agent and the placebo particles are accelerated toward the area of skin or mucosa using a needleless syringe device.

5 36. The method of claim 35, wherein the particles are accelerated toward the area of skin or mucosa at a velocity of about 200 to 3,000 m/sec.

37. The method of claim 33, wherein the particles comprising the therapeutic agent have a diameter predominantly in the range of about 0.1 to 250 μm .

10 38. The method of claim 37, wherein the placebo particles have a diameter predominantly in the range of about 10 μm to 50 μm .

15 39. The method of claim 33, wherein the placebo particles comprise about 1% to about 10% of the particles administered to the area of skin or mucosa.

20 40. The method of claim 33, wherein the placebo particles comprise a particle selected from the group consisting of a metal particle and a metal particle coated with a permeation enhancing agent.